

## REMARKS

Applicant replies to the Final Office Action dated May 14, 2009 within two months, and submits an RCE along with this Reply. Claims 1-13, 22-24, and 26 were pending in the application and claims 11-13, 22-24 and 26 were withdrawn from consideration. The Examiner rejects claims 1-10. Applicant cancels claims 4-6 without prejudice to filing one or more claims having similar subject matter in additional applications. Support for the amendments may be found in the originally-filed specification, claims, and figures. Applicant submits that no new matter has been introduced with these amendments.

### 35 U.S.C. §102

Examiner rejects claims 1-8 under 35 U.S.C. §102 as being anticipated by International Patent Application No. WO 00/67652 issued to Hehl ("Hehl"). Applicants respectfully disagree with this rejection as Hehl fails to disclose each and every element of the recited claims. However, Applicants amend certain claims to expedite examination and to further clarify the patentable features.

Hehl discloses "a bolt which extends beyond the surface of the fracture, whereby a sliding bushing having an inserted thread on the outer periphery thereof is screwed into the other part of the bone." (Abstract) Hehl further discloses sliding bushing 15 may comprise a stop device 13. (Illustrated in Fig. 4, 6, 9, and the Abstract) In such embodiments, stop device 13 prevents rearward translation of bolt 9 within sliding bushing 15 (i.e., stop device 13 prevents bolt 9 from displacing axially in more than one direction). (See Abstract) Specifically, Hehl's fig. 4 shows teeth on the bolt and a stop device on the bushing; fig. 6 shows an angled stop device on the bushing and teeth on the bolt; fig 8 shows a stop device on the bushing and square teeth on the bolt; fig. 9 shows a stop device on the bolt and teeth on the bushing.

Hehl fails to disclose each and every element of Claim 1. Hehl discloses a bolt, but Hehl does not disclose or contemplate a wire. As discussed in previous Remarks, a bolt and a wire do not have the same dictionary definition, and are significantly different structures with different purposes, benefits, disadvantages, etc. While Examiner makes an attempt to equate the two as identical structures, such an argument is far removed from how one of ordinary skill in the art would define the two terms. The Examiner cannot maintain a position that stands contrary to the common definition of the two words as used in the art. However, while Applicant continues to respectfully disagree with the Examiner's interpretation of the claimed element "wire", Applicant amends the claim to further clarify this element in order to expedite prosecution. As

such, Applicant asserts that Hehl does not contemplate, and teaches away from, at least "a flexible wire comprised of a thin metal . . . wherein said flexible wire is bendable without the use of tools and is able to be cut with a wire cutter," as recited in independent claim 1.

Hehl is very limited to only one way to drive the Hehl device into bone by "a bolt which extends beyond the surface of the fracture" If the bolt portion of Hehl were constructed with a bendable material (e.g., wire), then there would be no way by which the Hehl device could be driven into bone because the bendable material would not provide sufficient rigidity to drive the device. In other words, the Hehl device would cause the wire to bend or crumple which would be extremely dangerous in a surgical environment. Thus, if Hehl was constructed from a bendable material, the Hehl functionality would be destroyed.

Furthermore, while the figures in Hehl appear to depict some sort of threaded head, Hehl does not disclose "a head component having a tip, cutting threads, fastening threads, and a tool attachment" as recited in independent claim 1. Hehl also depicts a stop device engaging with teeth but fails to disclose or contemplate;

said cap such that said cap is configured to translate along said wire with **a portion of said inverse sawtooth configuration sliding over a portion of said sawtooth configuration, wherein said sawtooth configuration and said inverse sawtooth configuration** are configured to allow said cap to translate along said wire in only one direction, and wherein said **inverse sawtooth configuration includes a plurality of inverse teeth.**

also recited in independent Claim 1. While Examiner argues that a stop device could equate to be a single sawtooth, Applicant's claim amendments clarify the distinctions and render the stop device disclosed in Hehl an inadequate reference to anticipate any recited elements of Claim 1.

Moreover, the Examiner states that "Hehl disclose that one or more pawls 16 could be used as part of the second interface." While it is true that Hehl discloses a stop device, Hehl's stop device includes two parallel walls extending either perpendicularly or at an angle from the bolt or bushing. (fig. 4, 6, 8, and 9). In contrast, the presently claimed invention includes "wherein said sawtooth configuration is configured such that one side of each tooth is substantially perpendicular to a surface of said wire and the other side of said sawtooth is substantially angular to said surface of said wire, and wherein said sawtooth configuration includes a plurality of teeth," as recited in independent claim 1.

For at least the reasons provided above, Applicant respectfully submits that the Examiner has not made a prima facie case of anticipation of independent Claim 1.

Dependent claims 2-3 and 7-8 variously depend from independent claim 1, so Applicant asserts that dependent claims 2-3 and 7-8 are patentable for at least the same reasons for differentiating independent claim 1, as well as in view of their own respective features.

Accordingly, Applicant respectfully requests withdrawal of the 35 USC §102 rejection of claims 1-3 and 7-8.

**35 U.S.C. § 103**

The Examiner next rejects claims 1-10 under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 6,368,326 issued to Darkin et al. (“Darkin”) in view of U.S. Patent No. 5,893,850 issued to Cachia (“Cachia”), and U.S. Patent No. 6,050,998 issued to Fletcher (“Fletcher”). Applicant respectfully disagrees and Applicant asserts that the Examiner improperly combines the cited references and the references fail to adequately disclose all of the elements of the pending claims. Nonetheless, Applicant amends certain claims to expedite examination and to further clarify the patentable features.

Cachia discloses an elongated pin 26, a distal anchor 34, and a proximal anchor 36. (col. 4, lines 12-23). Cachia describes the proximal anchor 36 as a “radially outwardly extending collar 38 connected to a tubular housing 40 adapted to coaxially receive the pin body 32 there through.” (col. 4, lines 17-22) Despite the Examiner’s interchangeable use of the terms “pin” and “wire” when describing Cachia, Cachia **does not disclose a wire**. A pin and a wire are not equivalent structures. No person of ordinary skill in the art would equate the two to being the same structure. Furthermore, properties of pins are not obviously transferable to wires, cords, strands, or other flexible elongated material. For example, Cachia discloses a bone fixation device 24 comprising an elongate pin 26. The pin can be manufactured with medical grade construction materials, namely polymers such as high density polyethylene, nylon and polypropylene. (Col. 6: lns 16-25). Cachia further discloses the pin “must be of sufficient structural integrity for the intended application.” (Col. 5: lns 34-40). **Thus, the rigid pin disclosed in Cachia could not be locked in place by pinching with a locking screw, and would not be a suitable substitute.**

Darkin discloses a cord 22, an internal fastener 20, an external fastener 24, and a locking screw 28. Darkin further discloses that “fastener 24 is provided with a locking device 28 in the form of a screw that is received in a threaded bore in the fastener 24 and which, in this embodiment, clenches the cord between the fastener and screw to hold it in place.” (Col. 5 ln. 58-67). The flexible cord is a part of the principle of operation for the device. The ability to

lock the cord to the external fastener 24 is dependent on the cord being flexible. The use of the locking screw 28 allows external fastener 24 to travel in either direction with respect to the cord when not locked. **Trying to combine this teaching with Cachia is not obvious, as such a combination would change the principle of operation of Darkin by destroying flexibility and the external systems ability to travel in either direction.**

Fletcher discloses “a strand 22 and a pair of connector portions 24 and 26 on opposed ends of the strand 22” Fletcher further teaches that the connector portions “may be secured to the strand 22 by welding, crimping or other known connection techniques.” Fletcher exclusively illustrates connector portions integrated with the strand in the figures. Furthermore, Fletcher teaches that “the portions 24 and 26 may be turned on one another to form a loop 30. The barbs 28 of the portion 26 may then engage the barbs 28 of the socket 24. Because of the opposed angulation of the barbs on the respective portions, it is difficult or impossible to withdraw the portion 26 once it has been threaded through the socket 24.” Fletcher operates on the principle that the loop formed by connecting the two integral ends of the device provides the tension and pressure to make the device useful. Combining Fletcher with either Darkin or Cachia would change the principle of operation of Fletcher and frustrate its intended purpose. **Without the loop to provide tension, Fletcher is a useless device.** Neither Darkin nor Cachia can function as a loop by attempting to combine Fletcher with Darkin and Cachia, so Applicants assert that such a combination of references is not possible.

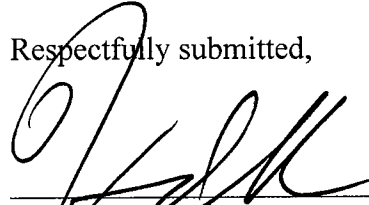
Furthermore, combining Fletcher with Darkin and Cachia fails to disclose several elements recited in Claim 1. **None of the three cited references individually or in combination disclose “a head component having a tip, cutting threads, fastening threads, and a tool attachment.”** While Darkin may show threads, Darkin does not show both cutting and fastening threads. Also, **none of the three cited references individually or in combination disclose “wherein said tool attachment is operable to receive a cannulated driver”**

For at least the reasons provided above, Applicant respectfully submits that the Examiner has not made a prima facie case of obviousness of independent Claim 1. Dependent claims 2, 3, and 7-10 variously depend from independent claim 1, so Applicant asserts that dependent claims 2, 3, and 7-10 are patentable for at least the same reasons for differentiating independent claim 1, as well as in view of their own respective features. Accordingly, Applicant submits that this rejection should be withdrawn.

**Conclusion**

In view of the above remarks, Applicants respectfully submit that all pending claims properly set forth that which Applicants regard as their invention and are allowable over the cited references. Accordingly, Applicants respectfully request allowance of the pending claims. The Examiner is invited to telephone the undersigned at the Examiner's convenience, if that would help further prosecution of the subject application. The Commissioner is authorized to charge any fees due to Deposit Account No. 19-2814. **This statement does not authorize charge of the issue fee.**

Respectfully submitted,

  
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